SENSICAINE TM EXTRA TOPICAL ANESTHETIC- benzocaine gel Safco Dental Supply Co.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

SensiCaineTM Extra Topical Anesthetic Gel Cherry Flavor

Active ingridients (in each gram)

Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

For oral mucosal use only, as directed by dentist. For the temporary relief of pain due to minor dental procedures.

Warnings

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: Do not use on patients with a history of allergies to local anesthetics such as benzocaine or other "caine" anesthetics.

Sore throat warning:If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsen, see your dentist or doctor promptly.

Do not use

- for teething
- in children under 2 years of age

When using this product Avoid contact with eyes. If contact occurs, flush with water.

If pregnant or breast feeding, consult a doctor before use.

KEEP OUT OF REACH OF CHILDREN. In case of overdose, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years of age and older: apply only amount needed to the oral mucosa to prevent or relieve pain
- children under 2 years of age: do not use

Other information

- Store at 59 86°F (15 30°C).
- Protect from freezing.

Inactive ingredients

flavoring, PEG 3350, PEG 400, sucralose. May contain D&C Red #33, FD&C Red #40, D&C Green #5, FD&C Yellow #5 as a color additive.

Questions or comments?

800-621-2178 www.safcodental.com

PRINCIPAL DISPLAY PANEL - Jar Label

SAFCO **SensiCaineTM Extra**

Topical Anesthetic Gel

Contains 20% Benzocaine

Cherry Flavor

For Professional Use Only

1 oz. (34 g)



Drug Facts

Active ingredients (in each gram) Benzocaine 200 mg

Purpose

Oral Anesthetic

Use

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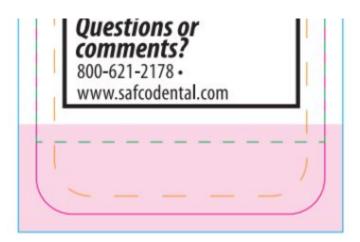
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	SENSICAINE TM EXTRA TOPICAL ANESTHETIC benzocaine gel											
Pı	roduct Informat	tion										
Pr	oduct T ype		HUMAN OTC DRUG	Ite m C	code (S	ource)	NDC:67239-0212		12			
Ro	ute of Administra	tion	DENTAL									
Active Ingredient/Active Moiety												
Ingredient Name Basis						Basis of Stre	ngth Strength					
Be	nzocaine (UNII: U3F	RS Y48 JW5) (Ber	zocaine - UNII:U3RSY48JW5)			Benzocaine		200 mg in 1 g				
Inactive Ingredients												
Ingredient Name								Strength				
Pol	lyethylene Glycol 3	350 (UNII: G2M	17P15E5P)									
Polyethylene Glycol 400 (UNII: B697894SGQ)												
Su	cralose (UNII: 96K6											
D&C RED NO. 33 (UNII: 9DBA0SBB0L)												
FD&C RED NO. 40 (UNII: WZB9127XOA)												
D&	C GREEN NO. 5 (U	NII: 8J6 RDU8 L9	ЭХ)									
FD	&C YELLOW NO.	5 (UNII: I753WB)	2F1M)									
Pr	oduct Characte	ristics										
Color		re	ed	Score								
Shape				Size								
Flavor		C	CHERRY	Imprint Code								
Contains												
Pa	ickaging											
#	Item Code]	Package Description		Marke	ting Start Date	Marl	keting E	End Date			
1	NDC:67239-0212-1	29 g in 1 JAR;	Type 0: Not a Combination Pro	duct (04/30/20	17						

Marketing Informat	Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date						
OTC MONOGRAPH NOT FINAL	part356	04/30/2017							
	Partooo	0 1100/2017							

Labeler - Safco Dental Supply Co. (020417380)

Registrant - Safco Dental Supply Co. (020417380)

Revised: 11/2018

Safco Dental Supply Co.